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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,637	12/22/1999	MARSHA A. MOSES	CMZ-083CPCN	5202

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
1651	22

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/469,637	Applicant(s) Moses et al.	
	Examiner Ralph Gitomer	Art Unit 1651	
<i>→ The MAILING DATE of this communication appears on the cover sheet with the correspondence address →</i>			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.			
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.			
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.			
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).			
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Sep 26, 2002</u>			
2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>130-162</u> is/are pending in the application.			
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>130-162</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
*See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)			
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)			
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____			
4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>14-15</u>			
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)			
6) <input type="checkbox"/> Other: _____			

The amendment received 9/26/02 has been entered and claims 130-162 are currently pending in this application. Please update the specification regarding related applications. The new 5 abstract must be submitted on a separate page. There may be a typo in the specification on page 32, line 21.

10 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or 15 improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

20 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be 25 commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 130-162 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,037,138. 30 Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass those of '138.

The above rejection is maintained for reasons of record.

The claims as presented are not properly searchable, hence no art is applied. After the following issues under USC 112 are 5 fully and properly addressed, a search will be conducted.

Claims 130-162 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while possibly being enabling for specific enzymes and prostate cancer detected by 10 specific MMP's, does not reasonably provide enablement for "a matrix metalloproteinase" or "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted present claims 134-148 are directed to various 15 cancers such as any epithelial, mesodermal, endodermal, hematopoietic origin, retina, skin, renal and lymphoma in general, and other claims include other tissues, but no such 20 types of cancer of such tissues are enabled by the present specification.

In claim 130 and all occurrences, "cancer" and "a matrix 25 metalloproteinase" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such cancer or proteinase would work in the instant invention. Note that a given organ, for example the kidney, is

prone to more than one type of cancer. Also, regarding the claims directed to ~~than MMP~~, it appears in the Tables in the present specification that not all gelatinases are effective in the claimed invention, only possibly two may be and they are not 5 characterized in any meaningful way.

~~A matrix metalloproteinase~~ reads on a multitude of Calpains among many other enzymes which are unlikely to work in the claimed invention.

"Cancer" reads on basal cell carcinoma to Ewings sarcoma 10 which are unlikely to work in the claimed invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative disorders and compounds claimed.
- 15 2. Amount of direction or guidance presented is insufficient to predict which disorders and substances encompassed by the claims would work.
3. Presence of working examples are only for specific disorders and substances and extension to other disorders and compounds has 20 not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related disorders and substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of disorders and compounds.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

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Applicant's arguments filed 9/26/02 have been fully considered but they are not persuasive.

Applicants argue that The Table 3 on page 22 shows various forms of cancer can be detected by the claimed method. And the specification enables specific enzymes, cancers, MMP's and cancers.

It is the examiner's position that Table 3 indicates that bladder, renal, lymphoma, testicular, and pheochromocytoma cannot be detected by the claimed method. In Table 2 on page 21 subjects with prostate cancer had either or both the presence of >150 kDa or 92kDa enzymes of some sort to some extent. No controls are seen. In Table 3 it wold appear rather random if the subjects had either or both of the same enzymes, no predictability is seen. And there are no controls shown in Table 3 either so no statistical significance can be determined.

The specification broadly mentions classes of enzymes, cancers, MMP's and cancers and does possibly provide enablement for the claimed invention for specific subsets of the above, but does not provide how to make and use the invention as claimed.

Claims 130-162 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all 5 occurrences.

There are many instances of lack of antecedent basis in the 10 claims, claim 130 line 1, ~~the diagnosis~~, line 6, ~~the presence~~ and many other occurrences. In claim 1 line 3, ~~a subject~~ does not related to the preamble subject. In claim 130, it is not seen what the correlation may be between the presence or absence of MMP with cancer. The preamble of claim 131 is unclear as to monitoring prognosis and monitoring diagnosis. Claim 131 is based upon using a marker but it does not recite how it is used. In claim 150 there is lack of antecedent basis for ~~the detection~~ 15 step~~s~~. There may be a typo in claim 156.

Any inquiry concerning this communication or earlier 20 communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If 25 attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status

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of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at
5 www.uspto.gov and click on the button **Patent Electronic Business Center** for more information.

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R. Gitomer

Ralph Gitomer
Primary Examiner
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